510(k) Summary

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c. Date prepared

January 14, 2008

d. Name of device

Trade Name	Spiro-Master PC-10 Spirometry System
Common Name	Diagnostic spirometer
Classification Name	Diagnostic spirometer
Classification Regulation	21 CFR 868 1840

e. Predicate devices

The Spiro-Master PC-10 Spirometry System is substantially equivalent to the following legally marketed devices

510(k)	k020102
Trade name	IQTeQ Spirometer 2001
Product code	BZG

510(k)	k002499
Trade name	Brentwood IQMarkTM Digital Spirometer
Product code	BZG

f. Description of the device

The "Spiro-Master PC-10 Spirometry System" is a handheld spirometer that connects to a Personal Computer (PC) via a Universal Serial Bus (USB 1 1 and 2 0) cable Windows™-based software on the PC runs the diagnostic spirometer application

The device consists of a plastic handle which houses the amplified pressure transducer, analog to digital converter, USB microcontroller and connection via a USB cable The electronics in the handle are powered by the 5 volts DC of the PC USB port The top of the handle has a connection for the flow sensor, which connects to the mouthpiece

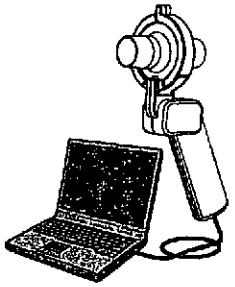

Figure 1 Spiro-Master PC-10 Spirometry System

A Pneumotach sensor is incorporated into the Spiro-Master PC-10 Spirometry System to detect airflow The flow sensor consists of two flow tubes that connect to each other around a sensor mesh ring which provides flow resistance A differential pressure across the mesh is generated depending on the inhalation/exhalation strength of the person being tested Inside the flow tube, the front and back of the mesh is connected to a pressure sensor through pressure outlet ports and tubes This differential pressure transducer measures the pressure difference across the flow sensor (mesh ring) as the air-stream passes through it The resulting pressure change is converted to a signal proportional to the airflow rate

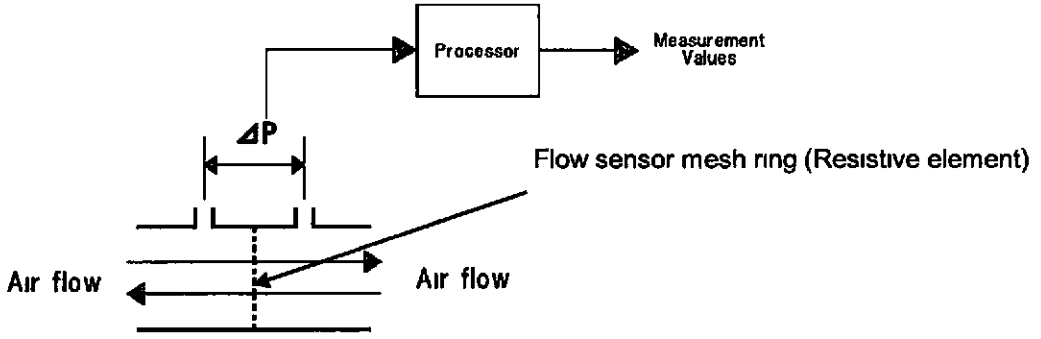

Figure 2 Block diagram of air flow detection circuit

The patient places their mouth on the mouthpiece, which is connected to a bacterial filter (KoKo Moe White Filter) between the mouthpiece and the sensor **The mouthpiece is a single-use, disposable component.**

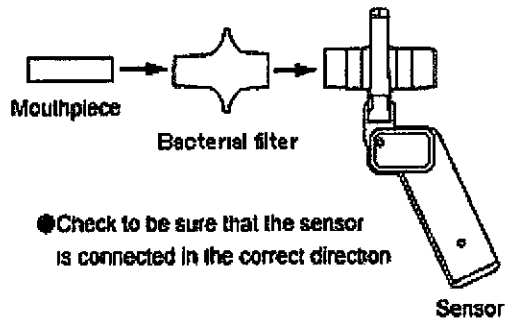

Figure 3 Patient connection components

The patient breathes as instructed through the mouthpiece The pressure transducer in the handle continuously transmits the differential pressure in the flow tube to the analog to digital converter The digitized 12 bit data is sent to the PC via the USB cable at 12 bit samples per second The Spiro-Master PC-10 Spirometry System application software (which requires Windows 98 or later), calculates the flow and integrates the flow to calculate volume The flows are calculated from the 12 bit data stream by applying a calibration polynomial algorithm All flow and volume data are calculated in real time for the flow-volume measurements which includes Peak Flow, Forced Vital Capacity, Forced Expiratory Flows Forced Inspiratory Vital Capacity as well as FEF and FIVC

The spirometer technician/operator uses the software on the PC to perform the tests The software includes a number of screens and 'buttons' that assist to logically perform the tests in the correct order The tests can be saved to the PC hard drive, printed (report format) and recalled for later review There are various parameters that are displayed to assist the technician in the quality control of the test procedure per the ATS 1994 update and the ATS 2005 standards The system calibration procedure requires six (6) varying strokes from a three (3) liter syringe

g. Intended Use, Indications for Use, and Environment

Intended Use
The Spiro-Master PC-10 Spirometry System is intended to acquire, view, store and print measures and waveforms of the exhaled breath of a person and evaluate pulmonary function These measures are used in the diagnosis and monitoring of lung diseases and interventions for the treatment of certain lung diseases The spirometer should only be used with patients able to understand the instructions for performing the test

Indication for Use
The Spiro-Master PC-10 Spirometry System is indicated for use with people of all ages, of either gender, excluding infants and neonates, to acquire, view, store and print measures and waveforms of the exhaled breath of a person and evaluate, access, describe, measure, or monitor

1 Symptoms, signs, or abnormal laboratory tests
2 Effects of disease on pulmonary function
3 Individuals at risk for pulmonary disease
4 Preoperative risk
5 Post-surgical prognosis
6 Pre-treatment health status
7 Therapeutic interventions
8 The course of disease affecting lung function
9 Persons exposed to pollutants
10 Adverse reactions to drugs with known pulmonary toxicity
11 Rehabilitation programs
12 Risks as part of an insurance evaluation
13 Individuals for legal reasons
14 Epidemiological surveys
15 Derivation of reference equations

Environment of Use
Places where a qualified clinician desires to take lung function measurement such as in hospitals, clinics, physicians' offices, laboratories and industrial health screenings

h. Statement of substantial equivalence

The characteristics of the Spiro-Master PC-10 Spirometry System are similar to those of the predicates described in Item e above The similarities are

- same intended use
- same operating principle
- same spirometry parameters
- same algorithms for spirometry parameters calculation
- same physical aspect (shape, size and weight)

There are no differences regarding safety or effectiveness Refer to Table 1 "Comparison Table" on the following two pages for a complete assessment

Table 1 Comparison Table

		Predicate Devices		
	Characteristic	IQTeQ Spirometer 2001	Brentwood IQmark™ Digital Spirometer	Spiro-Master PC-10 Spirometry System
1	PC Based	Yes	Yes	Yes
2	Physical configuration	The IQTeQ Spirometer2001 is a handheld spirometer that connects to a Personal Computer (PC) via a Universal Serial Bus (USB) port cable connection Windows based software on the PC runs the diagnostic spirometer application	Disposable Pneumotach Mouthpiece with handle (containing electronics) that connects directly to PC serial port via cable system software disk for PC installation	Spiro-Master PC-10 is a handheld spirometer that connects to a Personal Computer (PC) via a Universal Serial Bus (USB) port cable connection Windows based software on the PC runs the diagnostic spirometer application
3	Minimum PC requirements	Pentium II with USB port, 128mb RAM, Windows 98 Second Edition, CD-ROM drive, mouse, and 800X600 screen resolution	Pentium 100 MHz Processor, 16MB RAM (Windows 95&98), 32MB RAM (Windows NT), 64MB RAM (Windows 2000 Professional), 10MB HD space, Windows compatible printer	Windows 98, 2000, XP, Vista Keyboard, mouse, and a CD-Rom drive VGA display accommodating 1024x786, 1280x1024, or higher resolution At least one USB port
4	Power source	Power derived from USB port	Disposable Pneumotach Mouthpiece with handle two series AAA batteries (1 5v) inside handle	Power derived from USB port
5	ATS Spirometry performance recommendations	Complies (1994 Update)	Complies (1994 Update)	Complies (1994 Update) Complies (2005)
6	Cross contamination control	Disposable mouth piece & bacterial filter	Disposable mouth piece & bacterial filter	Disposable mouth piece & bacterial filter
7	Flow detection principle	Differential pressure Laminar flow resistance element	Disposable bi-directional pressure differential measuring pneumotach mouthpieces for expiratory/inspiratory testing	Reusable pressure differential measuring pneumotach
8	Flowmeter calibration method	Injection of known fixed volume from calibrated syringe	Injection of known fixed volume from calibrated syringe	Injection of known fixed volume from calibrated syringe
9	Display & printer used	PC monitor screen (LCD/CRT) and PC printer	PC monitor screen (CRT), alphanumerics and graphics	PC monitor screen (LCD/CRT) and PC printer

Table 1 Comparison Table (continued)

		Predicate Devices		
	Characteristic	IQTeQ Spirometer 2001	Brentwood IQmark Digital Spirometer	Spiro-Master PC-10
10	Graphic output	Flow-Volume loop, Volume/Time graph, predicted curve	Flow-Volume loop, Volume-Time curve, predicted curve, pre & post bronchodilator comparison	Flow-Volume loop, Volume/Time graph, predicted curve, pre & post bronchodilator comparison, bronchodilator-challenge
11	Tests performed	FVC, FIVC, PRE/POST Bronchodilator, Flow/Volume Loop, Volume/Time graph, SVC	FVC, F-V loop, MVV, VC(SVC), IVC, respiratory pattern, PRE/POST comparisons, bronchodilator-challenge	FVC, MVV, MV, VC(SVC), respiratory pattern, pre/post comparisons, broncho-challenge
12	Indices calculated (bold text indicates that an index used by Brentwood spirometer is also used by a listed predicate)	**FVC, FEV_1, FEV_3, FEV_6, FEV_1/FVC,** FEV_1/FEV_6, PEFR, **$FEF_{25\%}$, $FEF_{50\%}$, $FEF_{75\%}$,** FEF_{25-75}, **FEF_{75-85}, FIVC,** PIFR, **$FIV_{0.5}$,** FIV_1, FIV_3, FIV_1/FIVC, $FIF_{50\%}$, $FET_{100\%}$, SVC Extrapolated V%, and V(L), Peak risk time	**FVC, $FEV_{0.5}$, $FEV_{1.0}$, $FEV_{3.0}$, $FEV_{1.0}$/FVC;** FEF_{25-75}, **FEF_{75-85}, FEF_{25}, FEF_{50}, FEF_{75}, $FEF_{200-1200}$,** PEF, FIVC, **FIF_{50}, FEF_{50}/FIF_{50}, PIF, MVV, VC,** V_T, ERV, **RR,** t_E, V_{ext}, **$FIV_{0.5}$,** $FIV_{0.5}/FIV_{0.5}$, MV_T, IRV	SVC (VC), TV, **FVC, $FEV_{0.5}$, $FEV_{1.0}$, $FEV_{3.0}$,** $FEV_{6.0}$, **FEV_1/FVC,** FEV_1/SVC, MMEF, **PEF, FEF_{25}, FEF_{50}, FEF_{75}, FEF_{25-75}, $FEF_{200-1200}$,** FET, **FIVC, $FIV_{0.5}$,** $FIV_{1.0}$, **PIF, FIF_{50}, FEF_{50}/FIF_{50}, FIF_{50}/FEF_{50}, MVV, RR,** MV
13	Predictive models used (bold text indicates predicated model used by Brentwood spirometer also used by predicate)	**Crapo, ECCS,** Chernisk, **Morris, Knudoson**1983, **Hsu,** Schoenberg, NHANES III 1999 (Hankinson), **Plogar** 79	Adult **Kundson** 76 & 83 ,**Crapo(ITS), ECCS** 93 Pediatric **Plogar** 71 and **Knudson** 76 & 83u	**Crapo–Hsu, ECCS, ITS, Knudson, Morris, Polgar,** NHANES III 1999 (Hankinson)

As with the predicate devices, the Spiro-Master PC-10 Spirometry System has been tested for compliance to the ATS1994 (Update), IEC60601-1 and IEC60601-2 standards In addition the Spiro-Master PC-10 Spirometry System also complies with the ATS2005 standard

Therefore CHEST M I , INC believes that the Spiro-Master PC-10 Spirometry System is substantially equivalent to the predicate devices and does not raise any new questions regarding safety or effectiveness

i. Conclusion

Based on the above discussion and enclosed sections regarding substantial equivalence to predicate devices, CHEST M I , INC concludes that the Spiro-Master PC-10 Spirometry System is substantially equivalent to the IQTeQ Spirometer 2001 (k020102) and the Brentwood IQMark™ Digital Spirometer (k002499) and does not raise any new questions regarding safety or effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

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JAN 21 2009

Re K080921
Trade/Device Name Spiro-Master PC-10 Spirometry System
Regulation Number 21 CFR 868 1840
Regulation Name Diagnostic Spirometer
Regulatory Class II
Product Code BZG
Dated January 14, 2009
Received January 16, 2009

Dear Dr Kanai

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050 This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Anthony D. Watson for

Ginette Michaud, M D
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (If known) K080921 .

Device Name Spiro-Master PC-10 Spirometry System

Intended Use
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Environment of Use
Places where a qualified clinician desires to take lung function measurement such as in hospitals, clinics, physicians' offices, laboratories and industrial health screenings

Prescription Use X AND/OR Over-the Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number K080921